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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/700,672

11/05/2003

Kaoru Asano

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EXAMINER

BORIN, MICHAEL L

ART UNIT

PAPER NUMBER

1631

NOTIFICATION DATE

DELIVERY MODE

05/28/2010

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

Office Action Summary	Application No. 10/700,672	Applicant(s) ASANO ET AL.	
	Examiner Michael Borin	Art Unit 1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 March 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) 11-15 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>2/3/09, 4/18/08, 10/10/07, 01/16/04, 11/5/03</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of Claims

Response to restriction requirement filed 03/01/2010 is acknowledged. Applicant elected, without traverse, Group II, claims 1-10. Claims 11-15 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected groups.

Priority

Acknowledgment is made of applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d). The certified copy has been filed in this Application on 11/05/2003.

Information Disclosure Statement

Applicants' Information Disclosure Statements filed 2/3/09, 4/18/08, 10/10/07, 01/16/04, 11/5/03 have been received and entered into the application.

The information disclosure statement filed 01/16/2004 fls to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each cited foreign patent document; each non-patent literature publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. The reference cited in the

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Statement of 01/16/2004 is not in English. It has been placed in the application file, but the information referred to therein has not been considered.

Specification

Claim Rejections - 35 U.S.C. § 101

The following is a quotation of the 35 U.S.C. § 101:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title.

Claims 1-10 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

Claims 1-10 are drawn to a diagnosis support system for diabetes comprised of units described by functional language of data manipulation steps. While the systems may appear to be tangible, they are not a specific particular machine or apparatus. Claims 1-10 are directed to a "system for diagnosis" comprising various instructions. The claims are not directed to a machine or a composition of matter - there are no physical parts in the system addressed in the claim, the only limitations are descriptions of method steps. As such, the claim is directed to a software. Software, per se, is not statutory subject matter (see MPEP 2106 and *In re Nuijten*, 500 F.3d 1346, 84 USPQ 2d 1495 at 1500 (Fed. Cir. 2007)).

Thus, the claims are not viewed as directed to a statutory subject matter.

Claim Rejections - 35 USC § 102.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claims 1,6 are rejected under 35 U.S.C. 102(e) as anticipated by Kovatchev et al. (US 7,025,425) or Iliff (US 6,022,315)

The instant claims are drawn to a diagnosis support system which

- inputs clinical data (diagnostic data input unit)
- compares the data with criteria for analysis, such as insulin resistance (pathophysiological condition pattern analyzing unit)
- generates diagnosis based on the above comparison (diagnosis support information generating unit), and
- outputs the information (diagnosis support information output unit)

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Kovatchev et al. (US 7,025,425) teach method, system, and computer program product for the evaluation of glycemic control in diabetes from self-monitoring data.

The system

- collects blood data (viewed as a (diagnostic data input unit)
- compares the blood glucose (BG) data with database information (viewed as a (pathophysiological condition pattern analyzing unit)
- computes weighted deviation toward high blood glucose and estimated rate of change of blood glucose based on said collected BG data, and estimates HbA.sub.1c using a predetermined mathematical formula based on said computed WR and Dr (viewed as diagnosis support information output unit)
- outputs the information

See claims 11-19.

Iliff (US 6022315) teaches an automated medical diagnostic system, comprising:

- inputting data unit, a plurality of medical algorithms that select information,
- compare input data to “criteria of diagnosis”,
- scoring at least a portion of the received information and diagnoses a medical condition associated with the executed medical complaint algorithm if the score reaches or passes a threshold, and communicate the result.
- In particular, said system is applicable to diagnosis for diabetes – see col. 48. lines 40-43; col. 80, lines 42-46.

See claims 1,24.

It is the Examiners position that all the elements of Applicant's invention with respect to the specified claims are instantly disclosed or fully envisioned by the teaching of the references cited above

Claim Rejections - 35 USC § 103.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ilif in view of Yki-Jarvinen (Endocrine Reviews, vol. 13, No. 3, pages 415-431; reference provided by applicant).

Ilif reference is applied as above. Ilif does not teach particular criteria for diagnosis of diabetes addressed in dependent claim 2.

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Yki-Jarvinen teaches that hyperglycemia is a marker of poor metabolic control leading to diabetes, and a regulator of both insulin secretion and action. Further, the reference teaches that hyperglycemia triggers glucose toxicity, increase in insulin resistance, and decrease insulin secretion, each of which in itself is a marker of diabetes and also may precede and/or predict diabetes development. See Abstract, p. 415,417422,425,426.

Thus, it would be obvious to an artisan to be motivated to evaluate each of these parameters, hyperglycemia, glucose toxicity, insulin resistance, and insulin secretion, to evaluate status of a diabetic patient. To this end, it would be obvious to be motivated to use a computerized system that would allow to collect relevant data, compare them to said "criteria of analysis", and provide diagnostic information. As an example of such, it would be obvious to use a system of Ilif which provides all necessary functions for gathering, analyzing and outputting information.

With regard to claims 3,4,8,9, it would be obvious to an artisan to use conventional criteria of diagnosis, and to include any other relevant information.

With regard to claims 5, 10, the system of Ilif teaches constructing a biomodel using patients data and analysis information. See col.48, lines 10-25.

Prior art made of record

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure

Japanese publication 07-057018 is cited as another teaching of a medical diagnosing assistance system, and was provided by applicants.

Japanese publication 11-296598 is cited as another teaching of a biomodel generating unit to assist in diabetes diagnosis, and was provided by applicants.

Conclusion.

No claims are allowed

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Borin whose telephone number is (571) 272-0713. The examiner can normally be reached on 9am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marjorie Moran can be reached on (571) 272-0720. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael Borin/

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Primary Examiner, Art Unit 1631

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